AMENDED CLAIMS WITH MARKINGS TO SHOW CHANGES MADE

1. (Twice Amended) A maneuverable apparatus for remotely applying therapeutic energy to biological tissue comprising:

a flexible elongate member having a proximal end, a distal end and a longitudinal first lumen extending there between;

a deflection member disposed within the first lumen of the flexible elongate member and fixedly attached to said distal end of said elongate member, said deflection member having a proximal end, a distal end, and an inner lumen extending therebetween;

a conductor extending within said lumen of the deflection member for transmitting energy to said distal end of said elongate member, said conductor having a proximal end and a distal end; and

an energy source in communication with said proximal end of said conductor effective to transmit energy through said conductor;

wherein the deflection member is adapted to be flexed longitudinally relative to said elongate member, thereby causing said distal end of said elongate member to bend.

2. (Cancelled).

REMARKS

This Preliminary Amendment With Remarks is being filed with a Request for Continued Examination (RCE) pursuant to 37 C.F.R. §1.114. A final Office Action was issued on January 28, 2002 rejecting pending claims 1-24.

Applicants amend claim 1 to include all of the subject matter of cancelled claim 2. Thus, no new matter is added.

Applicants respectfully request reconsideration of the present application in view of the amendments set forth above and the remarks below.

Rejections under 35 U.S.C. §102

Claim 21

Claim 21 is rejected pursuant to 35 U.S.C. §102 as being anticipated by U.S. Patent No. 4,985,028 of Isner et al. (Isner). Claim 21 recites a method for treating trabecular tissue using a hollow flexible elongate member having a hollow deflection member disposed therein and fixedly attached to a distal end of the elongate member. The method includes the steps of introducing the flexible elongate member proximate to trabecular tissue, manipulating the deflection member longitudinally relative to the elongate member, thereby causing the distal end of the elongate member to bend, positioning a slidable conductor through the lumen of the deflection member proximate to the trabecular tissue, and transmitting energy to the distal end of the elongate member through the conductor such that the trabecular tissue is phototherapeutically modulated without damaging surrounding tissue.

Isner does not teach or suggest the steps of manipulating a deflection member to cause a distal end of an elongate member to *bend*, and positioning a *slidable* conductor through the lumen of a deflection member. In fact, Isner does not even disclose a device having a deflection member that is effective to cause bending, or one having a slidable conductor.

Isner discloses a catheter having a wye 26 with a primary branch 28 and a secondary branch 32. An inner catheter 22 (shown in the disassembled view in Figure 1) is mated to and extends through the primary branch 32 of wye 26 along the entire length of the device, and includes a fixation wire 42 slidably disposed therein. The proximal end of the fixation wire 42 is mated to a piston 40 which, in use, if effective to slide the fixation wire proximally and distally. The fixation wire ***does not cause bending*** of the distal end of the catheter, but rather provides rigidity to the catheter to maintain the position of the distal tip during use. (See Col. 3, lines 33-36, and Col. 4, lines 11-15.) Isner does not teach or suggest any type of control or deflection member for effecting movement of the distal end of the device. Rather, the distal end of the catheter is merely slid into the ventricle of a patient's heart, and the fixation wire is moved proximally into the distal end to prevent transverse motion of the catheter during use. (See Col. 4, lines 42-48.) Accordingly, Isner does not teach the step of manipulating a deflection member longitudinally relative to an elongate member to cause a distal end of the elongate member to bend, as recited in claim 21.

Isner also fails to teach or even suggest the recited step of positioning a slidable conductor through the lumen of a deflection member proximate to a tissue site. At the outset, for the same reasons stated above, Isner cannot teach the step of positioning a slidable conductor through the lumen of a deflection member since Isner does not teach any type of deflection member. Regardless, even if Isner were considered to teach a deflection member, Isner does not teach or even suggest the use of a *slidable conductor*. The catheter device disclosed by Isner includes a sheath 34 extending through the secondary branch and having an optical fiber 52 disposed therein. The optical fiber 52 is fixedly disposed within the sheath 34 and mates to a metallic cylinder 68 attached to the inner catheter 22 at the distal end of the device. Since the optical fiber 52 is *fixedly* disposed within the sheath, the optical fiber 52 is *not movable*, and therefore cannot be *slidably* positioned through a lumen.

Claim 21, therefore, represents allowable subject matter.

Claims 21 & 22

The Examiner further rejects claims 21 and 22 pursuant to 35 U.S.C. §102 as being anticipated by U.S. Patent No. 5,549,109 of Samson et al. (Samson).

Claims 21 and 22 each recite a method including the steps of introducing a flexible elongate member having a deflection member disposed therein proximate to a tissue site, manipulating the deflection member longitudinally relative to the elongate member, thereby causing the distal end of the elongate member to bend, positioning a slidable conductor through a lumen in the deflection member proximate to a tissue site, and transmitting energy to the distal end of the elongate member through the conductor to treat tissue.

Samson does not teach, or even suggest, a device having any type of control or deflection mechanism for positioning the distal end of the device. Rather, Samson discloses a catheter having a guide wire adapted to map electrical activity disposed therein. The guide wire is formed from insulated conductive wires or filaments braided or woven together, and attached at the distal end to sensors. In use, the catheter and guide wire are introduced into a patient through a femoral artery or vein and progressed to the desired treatment site. A signal is then transmitted through the guide wire to treat and/or map tissue. The guide wire is merely used to treat and/or map tissue, and does not provide any type of control over the catheter. Accordingly, Samson does not teach the step of manipulating a deflection member relative to an elongate member to cause a distal end of the elongate member to bend, as is required by claims 21 and 22. Samson also cannot be considered to teach the step of positioning a slidable conductor through a lumen of the deflection member since Samson does not disclose any type of deflection member. Accordingly, claims 21 and 22 are not anticipated by Samson, and therefore represent allowable subject matter.

Rejections under 35 U.S.C. §103

Claims 1-12, 15-20, & 23

Claims 1-12, 15-20, and 23 are rejected pursuant to 35 U.S.C. §103 as being obvious over Kittrell in combination with U.S. Patent No. 5,306,245 of Heaven. The Examiner argues that Kittrell teaches the device as claimed except for the particular deflection member. Thus, the Examiner relies on Heaven to teach a wide variety of deflection members and argues it would have been obvious to employ one of the deflection members disclosed by Heaven in the device of Kittrell. Applicants respectfully disagree.

Independent claims 1, 17, 21, and 23 each recite a device, or method of using a device, having a flexible elongate member and a hollow deflection member disposed within the flexible elongate member. The deflection member is *attached* to the distal end of the flexible elongate member, and is adapted to move to cause the distal end of the elongate member to bend. Neither Kittrell nor Heaven teach or suggest the claimed device or method of using the device.

Kittrell is directed to a laser catheter having an optical fiber disposed within a catheter for delivering a laser beam intravascularly. A control wire, which is merely a solid guide wire, is affixed near the distal end of the catheter for changing the position of the distal tip. As admitted by the Examiner, Kittrell does not teach or suggest a deflection member having an inner lumen formed therein, and having a distal end attached to the distal end of the catheter.

Heaven does not remedy the deficiencies of Kittrell. Heaven discloses a steerable catheter which is adapted to receive a medical device. The catheter includes an outer sheath 14 surrounding a tubular member 2 having a cut out portion or articulating portion formed therein. The tubular member 2 is *slidably* disposed within the outer sheath 14. As a result, the tubular member (e.g., deflection member) is not *attached* to the distal end of the outer sheath (e.g., catheter), as is required by the pending claims of the present invention. Moreover, since the tubular member is not attached to the outer sheath, the tubular member cannot be used to cause

the outer sheath 14 to bend. Instead, a guide wire 8 is attached to a distal end of the tubular member and is effective to cause the tubular member to bend at the cut out portion. Thus, even if Heaven and Kittrell were combined, neither reference teaches or suggests the present invention. Independent claims 1, 17, 21, and 23 therefore represent allowable subject matter. Claims 2-16, and 18-20 are allowable at least because they depend from an allowable base claim.

Claims 13 & 14

The Examiner further rejects claims 13 and 14 as being unpatentable over Kittrell combined with Heaven as applied to claim 12, and further in view of U.S. Patent No. 5,129,895 of Vassiliadis et al. (Vassiliadis). The Examiner relies on Vassiliadis to teach the use of a gold coating. For all of the aforementioned reasons, Applicants submit that claims 13 and 14 are not obvious in view of Kittrell combined with Heaven. Vassiliadis does not remedy the deficiencies of Kittrell or Heaven. Vassiliadis is directed to a fiber optic probe for use during a laser sclerostomy procedure. Vassiliadis is unrelated art, and does not provide any type of steering mechanism, or even teach an ablation instrument. Accordingly, claims 13 and 14 are not obvious in view of Kittrell, Heaven, and Vassiliadis, and therefore are allowable.

Claim 24

Claim 24 is further rejected as being obvious over Samson combined with Kittrell. As previously stated, the device disclosed by Samson does not include any type of control or deflection mechanism for positioning the distal end of the device. Accordingly, since neither Kittrell nor Samson teach or even suggest any type of deflection member, claim 24 is allowable.

Conclusion

The present invention provides a novel, non-obvious steerable ablation instrument having a single deflection member disposed within a flexible elongate member. The deflection member, e.g. inner tube, does not require the use of a guide wire for applying a force to the instrument to

bend the instrument, but rather is the "guide wire" which is used to bend the flexible elongate member. None of the cited references, either alone or combined, teach or suggest the present invention. Accordingly, Applicants submit that claims 1-24 are in condition for allowance. A clean version of the pending claims is attached hereto. In the event that the above amendments and remarks are not deemed to place this case in condition for allowance, an opportunity to interview with Examiner Shay is requested. Applicants encourage the Examiner to telephone the undersigned upon receipt of this response to discuss any issues that may remain.

Respectfully submitted,

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